EXHIBIT F

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

March 22, 2019

VIA Electronic Mail and UPS

Jeffrey Coopersmith, Esq.
Davis Wright Tremaine LLP
505 Montgomery St., Suite 800
San Francisco, CA 94111

Re: Subpoena issued to United States Food and Drug Administration in *Securities and Exchange Commission v. Ramesh "Sunny" Balwani;* Civil Action No. 5:18-CV-01603-EJD (N.D. Cal.)

Dear Mr. Coopersmith:

This letter responds to the third-party subpoena to the United States Food and Drug Administration (FDA) in the above-referenced case, issued by you on March 15, 2019, to Rebecca Falk in the Department of Justice (DOJ). FDA had not waived service or authorized Ms. Falk to accept service on its behalf prior to your firm's purported "re-issuance" of its earlier subpoena by way of an email to Ms. Falk, and FDA has no record of any other service of this document. In an effort to move this matter forward, however, FDA has authorized Ms. Falk to accept service specifically of this subpoena on its behalf. This letter sets forth our objections to your subpoena pursuant to Rule 45(d)(2)(B) of the Federal Rules of Civil Procedure.[1]

Your subpoena requests 20 broad categories of documents, correspondence, and communications (hereafter, "documents") referring to or relating in any way to Theranos, Inc. (Theranos), Elizabeth Holmes, and Ramesh "Sunny" Balwani, from the eight and a half year period from January 2010 through June 2018, including, among other things, internal FDA documents and documents between FDA and the following entities: DOJ, the Department of Defense (DOD), the Centers for Medicare & Medicaid Services (CMS), members of Congress, the media, the health care industry, laboratories and laboratory associations.

When FDA initially received your subpoena on September 14, 2018, it was unaware that you were already in possession of more than 40,000 pages provided by FDA to the SEC in connection with its civil case against Mr. Balwani and/or to DOJ in connection with its criminal case against Mr. Balwani. Because FDA did not know this, the agency began processing your subpoena by preparing and producing the documents that FDA gave to the SEC and DOJ, and it provided you over 4,200 pages of documents in four separate

[1] Because FDA has not completed its review of all responsive documents, this written objection may not include all possible bases for objection. FDA reserves the right to assert later that additional bases exist for objecting to the disclosure of the requested documents.

productions between October 16 and 24, 2018. However, once FDA became aware that you already had the documents the agency had previously produced to the SEC and DOJ, we informed your colleagues Ben Byer and Amanda McDowell that we were going search for new responsive documents and emails responsive to the subpoena. During multiple calls, we explained the steps we were taking and why it would speed up the process if we received a waiver from Theranos, which would allow FDA to produce lesser-redacted documents more quickly. FDA made several unsuccessful attempts to obtain a waiver in this case, but Mr. Byer stated that he would obtain a waiver that would permit FDA to produce documents containing Theranos' trade secret and confidential commercial information (CCI). We have not yet received a waiver.

Although FDA has not yet had collected and reviewed all documents that may be responsive to your subpoena, based on our initial assessment, it appears that the Federal Rules of Civil Procedure, federal law, and discovery privileges may prevent FDA from disclosing some portion of the requested documents to you.

Below, I explain the grounds for these objections based on our preliminary evaluation.

Prohibition on FDA's Disclosure of Trade Secret and Confidential Commercial Information

FDA is specifically prohibited from releasing trade secret information obtained under certain of its regulatory authorities in a judicial proceeding that is not brought under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and FDA is also prohibited from releasing trade secrets and CCI regarding devices obtained through the agency's regulatory and inspectional authorities, 21 U.S.C. § 360j(c). In addition, the Trade Secrets Act, 18 U.S.C. § 1905, prohibits FDA from releasing trade secrets and CCI unless otherwise authorized by law. Further, FDA regulations provide that trade secrets and CCI are not available for public disclosure. *See* 21 C.F.R. § 20.61. Accordingly, FDA is unable to produce any responsive information that would reveal trade secrets and/or confidential research, development, or commercial information. *See also* Fed. R. Civ. P. 45(d)(3)(B)(i).

The extent to which the agency will be required to redact responsive documents prior to producing them to you, as well as the speed at which FDA will be able to produce these documents, largely depends upon whether Theranos or its assignee authorizes FDA to release trade secrets or CCI to Mr. Balwani and whether the parties in the above-referenced case have entered into an acceptable protective order that would protect the trade secrets and CCI that FDA would otherwise need to identify and withhold. Should Theranos or its assignee provide FDA with an acceptable waiver, FDA would not be required to redact the company's trade secrets and CCI from the responsive documents; the agency would, however, still must review and redact any third party's trade secrets or CCI from responsive documents.

Objections Based on Other Privileges

FDA has agreed to waive its deliberative process privilege with respect to Theranos documents. However, your subpoena seeks disclosure of materials that are or contain attorney-client communications, attorney work product, personal privacy information, privileged investigatory files, and/or other protected information, and FDA objects to disclosure on those bases as well. *See* Fed. R. Civ. P. 45(c)(3)(A)(iii); *see also* 21 C.F.R. §§ 20.62, 20.63, 20.64. Before any documents can be provided to you, FDA will have to review and redact any such privileged information.

Responsive Documents Are Available from Another Source

FDA also objects to your subpoena to the extent that it requests documents which, even if contained in FDA files, are available elsewhere. Specifically, you request documents that may belong to, or relate to activities of Mr. Balwani, a party in the underlying litigation and Theranos, the company for which Mr. Balwani served as President and Chief Operating Officer, as well as non-government third parties. Accordingly, we object to your request for these documents under Rule 45, Rule 26(b)(2)(C), and 21 C.F.R § 20.51, as the documents could be obtained more easily from Mr. Balwani or non-government third parties, thus sparing the use of taxpayer resources.

The Subpoena is Overly Broad and Unduly Burdensome

The subpoena is also overly broad and unduly burdensome. *See* Fed. R. Civ. P. 45(d)(1), (d)(3)(A)(iv); 21 C.F.R § 20.50. As noted, your subpoena is quite expansive and potentially covers a large number of documents over a long-time period. As discussed above, your requests encompass documents that may contain trade secrets and CCI protected from release or disclosure under applicable statutes, regulations, and privileges. Thus, responding to your subpoena as currently drafted requires a significant amount of time to collect and review a large number of potentially responsive documents for possible production.

Moreover, FDA is currently faced with many other voluminous document requests, including Freedom of Information Act requests, Congressional requests, and other subpoenas, and the agency employs a queue approach to processing these document requests. Given the existing document production demands on FDA and the time needed to review the large number of documents responsive to your subpoena, it will take a significant amount of FDA employee time to prepare these documents for production in litigation in which FDA is not a party. This effort would deprive FDA of valuable resources and put a strain on the agency's resources. Your subpoena imposes a burden on FDA that is not proportional to the agency's role and relevance in the SEC case. Accordingly, we object to the subpoena pursuant to Rule 45 and 21 C.F.R § 20.50 as overly broad and unduly burdensome.

Objection Based on Geographical Limits

Pursuant to Rule 45(d)(3)(A)(ii), a district court must quash or modify a subpoena if it "requires a person to comply beyond the geographical limits specified in Rule 45(c)." Under Rule 45(c)(2), "[a] subpoena may command: (A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person . . . ." The present subpoena, requires FDA, a non-party, to produce documents in San Francisco, CA. The records responsive to your subpoena are located in Silver Spring, MD. Because the subpoena does not meet the requirements of Rule 45(c)(2), the subpoena is invalid and unenforceable. See Fed. R. Civ. P. 45(c)(2) & (d)(3)(A)(ii).

Conclusion

Notwithstanding the foregoing, FDA is committed to working with you to resolve this matter and to produce documents in a manner that is consistent with federal law, agency procedures, and FDA's commitments and obligations in other matters, and which does not subject the agency to an unreasonable burden. The agency has already expended a significant amount of resources to respond to document requests in connection with the SEC's civil case and DOJ's criminal case against your client and will continue to do so as it reviews and prepares additional responsive, non-privileged documents for production in response to your subpoena. We are doing our best to get you the documents you want as quickly as possible, considering the large volume of documents and the agency's other pressing responsibilities. Once you have obtained a waiver from the Theranos assignee and the Supplemental Stipulated Protective Order governing FDA and CMS documents is entered by the Court, FDA will produce additional records to you in response to the subpoena.

If you have any further questions, please contact AUSA Rebecca Falk at 415-436-7022.

Sincerely,

Laura J. Draski -S

Digitally signed by Laura J. Draski -S
Date: 2019.03.22 15:20:14 -04'00'

CAPT Laura Draski, PhD
Acting Director
Office of Strategic Planning and Operational Policy
Office of Regulatory Affairs
U.S. Food and Drug Administration